A Feasibility Study of the Surpass Aneurysm-Embolization (SAE) System in Intracranial Arteries

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The purpose of this study is to evaluate safety and performance of the Surpass Aneurysm-Embolization System.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33249

Source
ToetsingOnline

Brief title
A Feasibility Study of the SEA-System in Intracranial Arteries

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
localised bulging / ballooning of a blood vessel

Research involving
Human

Sponsors and support

Primary sponsor: Surpass Medical Ltd
Source(s) of monetary or material Support: Surpass Medical Ltd

Intervention

Keyword: Embolization, Intracranial aneurysma, Intracranial flow-divertion

Outcome measures

Primary outcome

The adverse events assessment for all enrolled subjects in the study includes:

•Incidence of adverse events assessed during the procedure, immediately post-procedure through discharge.

The adverse event assessment for all subjects with a deployed device includes:

•Incidence of adverse events assessed during the procedure, immediately post-procedure, at discharge, at thirty days and six months after treatment.

The neurological status for all subjects with a deployed device includes:

•Clinical/neurological outcome using neurological evaluations (NIH Stroke Scale, Modified Rankin Scale) by qualified personnel after the procedure, at thirty days and six months after treatment compared to the baseline evaluation.

The technical feasibility for all subjects with a deployed device includes:

•Evaluation of percent occlusion assessed at six months after treatment.

•Successful stent placement (device success defined as device placed where

intended with appropriate wall apposition) angiographically assessed

immediately post-procedure.

Secondary outcome

none

Study description

Background summary

Aneurysms are a challenge to treat both surgically and endovascularly. During surgical clipping, a section of the skull is removed in order to create a hole to see the aneurysm. A small metal clip is then placed around the neck of the aneurysm, blocking any blood from entering. This treatment is associated with a high incidence of morbidity and mortality. Surgical clipping may be difficult or impossible depending on the aneurysm*s location in the brain or if there is no true neck (opening) of the aneurysm present.

Endovascular therapy has been limited to parent artery occlusion (if there is adequate collateral flow), or treatment with embolic coils (small metal coils), with or without the use of balloon dilatation and/or stent implantation.
Balloon dilatation, however, has limitations because the temporary interruption of blood flow in the parent artery increases the risk of local and distal thromboembolism. Furthermore, balloon dilatation is not applicable in wide-neck or complex aneurysms, and its long-term efficacy has not been proven. Aneurysms may be difficult to treat with embolic coils alone because of the significant risk of coil prolapse into the parent artery.
The goal of endovascular treatment is complete thrombosis of the aneurysm while preserving the parent and side-branch artery lumen. Endovascular coiling has a much lower mortality and morbidity rate than surgery, however, large and giant aneurysms are associated with over 40% of relapse necessitating re-treatment of the patient.

The device under investigation has a big advantage over surgery or coiling: with the use of the Surpass Aneurysm-Embolisation System there is no need for placement of coils, resulting in a decrease in procedure time and cost. In addition, risk of relapse after treatment of the aneurysm with the Surpass Aneurysm-Embolisation System is estimated to be < 5% (animal study showed > 97% aneurysm occlusion over a period of six months) while maintaining the lower mortality / morbidity rate of coiling.

Study objective

The purpose of this study is to evaluate safety and performance of the Surpass Aneurysm-Embolization System.

Study design

This is a single-center, prospective, non-randomized study including up to 10 subjects treated with the device. Subjects will receive a follow-up evaluation at thirty days (+ two weeks) and at six months (± four weeks) with a follow-up angiography at six months.

Intervention

Treatment with the Surpass Aneurysm-Embolization System

Study burden and risks

The study is designed to minimize potential risks and complications in the subjects. Risks associated with using the Surpass Aneurysm-Embolization System are believed to be the same as those associated with intracranial catheterization or intracranial stent placement. The following complications associated with intracranial catheterization or intracranial stent placement have been identified as possible (anticipated) complications and may occur:
•Aneurysm recanalization
•Allergic reaction including, but not limited to, contrast, and medications
•Arrhythmia
•Arteriovenous fistula
•Death
•Dissection
•Emboli (air, tissue or thrombotic emboli)
•Emergent neurosurgery
•Failure to deliver the device to the intended site
•Hemorrhage
•Hematoma
•Hypotension / Hypertension
•Incomplete Aneurysm Occlusion
•Infection
•Injury to normal vessels or tissue
•Ischemia
•Occlusion of side branch
•Myocardial infarction
•Neurologic deficit
•Pain at insertion site
•Perforation
•Pseudoaneurysm
•Renal failure
•Rupture, vessel or aneurysm

•Seizures
•Stenosis of treated segment
•Device migration / embolization
•Device thrombosis / occlusion
•Stroke / cerebrovascular accident
•Total occlusion of treated segment
•Vasospasm
•Vessel thrombosis

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Subject understands the nature of the procedure and provides written informed consent.
•Subject is willing to return to the investigational site for the thirty day and six month follow-

up evaluations.
•Age 18 years to 80 years.
•Subject with a non-ruptured saccular, dissecting or fusiform intracranial aneurysm arising from a parent vessel with a diameter of >= 2mm and <= 6mm.

Exclusion criteria

•Pregnancy and lactating women
•Participation in another investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this study
•Allergy or contraindication to aspirin, clopidogrel, heparin, local or general anesthesia
•History of life threatening allergy to contrast dye.
•Major surgery within previous 30 days or planned in the next 90 days after enrollment date.
•Dementia or psychiatric problem that prevents the patient from completing required follow up
•Co-morbid conditions that may limit survival to less than one year
•Subject with anatomy not appropriate for endovascular treatement due to severe intracranial vessel tortuosity or stenosis, or intracranial vasospasm not responsive to medical therapy.
•Subject with an intracranial mass (tumor (except meningioma), abscess, or other infection), or is undergoing radiation therapy for carcinoma or sarcoma of the head or neck region.
•Subject has a history of bleeding diathesis or coagulopathy, international normalized ratio (INR) greater than 1.5, or will refuse blood transfusions.
•Subject has a serum creatinine level greater than 2.0 mg/dL (within 7 days of procedure) which the investigator determines restricts the use of contrast agents.
•Subject has a previously implanted intracranial stent associated with the symptomatic distribution within the past 12 weeks prior to enrollment date
•Stenting, angioplasty, or endarterectomy of an extracranial (carotid or vertebral artery) or intracranial artery within 30 days prior to enrollment date
•Subject has a previously implanted carotid stent associated with the symptomatic distribution within the past 12 weeks prior to enrollment date
•Subject has uncontrolled atrial fibrillation or known cardiac disorders likely to be associated with cardioembolic symptoms.
•Subject had a subarachnoid hemorrhage within 12 weeks prior to the enrollment date.
•Subject with resistance to ASA and/or Clopidogrel.
•Subject with two or more aneurysms in associated distribution - unless the device is used to treat both aneurysms.
•Subject has a non-treated arteriovenous malformation (AVM) in the territory of the target aneurysm.
•Target aneurysm is expected to require more than one device.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Surpass Aneurysm-Embolization System
Registration:	No

Ethics review

Approved WMO

Date:	21-05-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28760.091.09